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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/985,708	11/06/2001	Richard L. Prass	2401.0266C	4274

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Epstein, Edell, Shapiro, Finnan & Lytle, LLC  
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Rockville, MD 20850

EXAMINER

FOREMAN, JONATHAN M

ART UNIT PAPER NUMBER

3736

DATE MAILED: 07/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/985,708

Applicant(s)

PRASS, RICHARD L.

Examiner

Jonathan ML Foreman

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**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 February 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 27-32 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 10-26 is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-9 is/are rejected.
- 7) ☒ Claim(s) 4 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |  |
|--|--|
| <p>1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)</p> <p>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p> <p>3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br/>Paper No(s)/Mail Date <u>2/19/03</u>.</p> | <p>4) <input type="checkbox"/> Interview Summary (PTO-413)<br/>Paper No(s)/Mail Date. _____</p> <p>5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)</p> <p>6) <input type="checkbox"/> Other: _____</p> |
|--|--|

## DETAILED ACTION

### *Information Disclosure Statement*

The information disclosure statement filed 2/19/03 complies with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. It has been placed in the application file, and the information referred to therein has been considered by the examiner as to the merits.

### *Election/Restrictions*

1. Claims 27 – 32 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 1/5/05.

### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1 – 3 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,807,643 to Rosier.

In regards to claims 1 – 3 and 5, Rosier discloses a method for intraoperative neurophysical monitoring with at least one electrical stimulus probe (Col. 2, lines 42 – 52) as an intraoperative aid in defining the course of a nerve structure by monitoring electromyographic activity within the nerve structure including contacting the nerve structure with the probe (Col. 3, lines 3 – 7), detecting a stimulus probe impedance change resulting from the stimulus probe nerve contact; and triggering a sequence of pre-programmed intraoperative neurophysical monitoring algorithm steps (Col. 3, lines 57 – 65) including closing a circuit between a current source and the stimulus probe to provide

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stimulus current to the nerve (Col. 2, lines 53 – 56). Rosier discloses generating a visible or audible annunciation of nerve tissue contact impedance. Rosier discloses generating a pre-programmed sequence of stimulus pulses; and storing the measured responses collected from the electrodes (Col. 4, lines 44 – 48).

4. Claims 1 and 6 – 9 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,215,100 to Spitz et al.

In regards to claims 1 and 6 - 9, Spitz et al. discloses a method for intraoperative neurophysical monitoring with at least one electrical stimulus probe as an intraoperative aid in defining the course of a nerve structure by monitoring electromyographic activity within the nerve structure including contacting the nerve structure with the probe (Col. 5, lines 26 – 35), detecting a stimulus probe impedance change resulting from the stimulus probe nerve contact; and triggering a sequence of pre-programmed intraoperative neurophysical monitoring algorithm steps (Col. 13, lines 19 – 44). Spitz et al. discloses analyzing the stored, measured responses collected from the enervated muscle structures, to determine the average response amplitude, the peak-to-peak response amplitude and response threshold (Col. 13, lines 57 – 64; Col. 14, line 67 – Col. 15, lines 31) .

***Allowable Subject Matter***

5. Claim 4 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

6. Claims 10 – 26 are allowed. The prior art fails to teach or fairly suggest a method for intraoperative neurophysical monitoring, including placing a first electrode in a muscle enervated by a selected nerve; placing a second electrode in a muscle not enervated by the selected nerve;

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stimulating the nerve; monitoring the effect of the stimulation of the nerve; and actuating an alarm if the stimulation is observed on the first electrode but not on the second electrode. The prior art fails to teach or suggest a method for detecting and analyzing a neurophysiological signal in the body including defining a first probe sampling window of time having a first selected duration; defining a second probe sampling window of time having a second selected duration and being delayed with respect to said first probe sampling window of time by a selected inter-probe interval of time; contacting a nerve structure in the body; sensing a continuous and time varying electromyographic waveform from the nerve structure; storing said nerve structure electromyographic waveform in memory; rectifying said nerve structure electromyographic waveform; and generating a continuous threshold waveform by processing the rectified nerve structure electromyographic waveform through said first probe sampling window and through said second probe sampling window and subtracting the instantaneous value of the waveform power in said second probe window from the instantaneous value of the waveform power in said first probe window. The prior art fails to disclose or suggest a method for controlling a neurophysiological monitoring instrument connected to a stimulus probe and one or more electrodes for monitoring electromyographic activity in nerve and muscle structures in the body including connecting a first circuit to the stimulus probe for sensing an electrical parameter that changes in response to touching tissue structures in the body, said first circuit being adapted to generate a stimulus probe sensed signal pulse; connecting a controller connected to the first circuit for receiving the stimulus probe sensed signal, the controller being adapted to execute an algorithm including a plurality of instrument control commands and a plurality of selected patterns of stimulus probe sensed signal pulses; placing a stimulus probe in proximity to tissue structures in the body; sensing said electrical parameter changing in response to touching tissue structures in the body; generating a pattern of stimulus

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probe sensed signal pulses similar to one of the selected patterns of stimulus probe sensed signal pulses; and generating an instrument control command in response to detecting the pattern of stimulus probe sensed signal pulses.

***Conclusion***

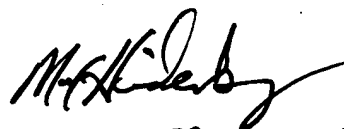
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (571)272-4724. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



JMLF



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